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Original Research

# Effects of Functional Electrical Stimulation on Reducing Falls and Improving Gait Parameters in Multiple Sclerosis and Stroke

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## Abstract

**Background:** Loss of neuromuscular control of the ankle joint is a common impairment in neurologic conditions, leading to abnormal gait and a greater risk of falling. Limited information, however, is available on the effectiveness of functional electrical stimulation (FES) on reducing falls, and no studies have investigated its usefulness in improving lower limbs kinematics related to foot clearance and energy recovery.
**Setting:** Clinical setting.
**Study Design:** Prospective longitudinal study.
**Participants:** Twenty-four subjects, 14 people with multiple sclerosis (mean age $\pm$ standard deviation 50.93 $\pm$ 8.72 years) and 10 people with stroke (55.38 $\pm$ 14.55 years).
**Methods:** The number of falls was assessed at baseline and after 8 weeks, and a clinical assessment was assessed at the baseline, 4-week, and 8-week time points. A subsample of the 24 subjects comprising 5 people with multiple sclerosis and 5 people with stroke performed a gait analysis assessment at baseline and after 4 weeks. After receiving the equipment and the training schedule, subjects performed daily home walking training using FES for 8 weeks.
**Main Outcome Measurements:** The main outcomes were (1) the number of falls, (2) foot clearance, and (3) energy recovery.
**Results:** A reduction in the number of falls was observed from baseline (n = 10) to the 8-week assessment (n = 2), $P = .02$. Foot clearance increased (+5.26 mm, $P = .04$) between the baseline without FES and at 4 weeks with FES (total effect). No statistically significant differences were found in energy recovery between baseline and 4 weeks.
**Conclusions:** The use of FES had an impact on gait, specifically reducing the number of falls and improving walking. A specific effect at the ankle joint was observed, increasing foot clearance during the swing phase of gait. This effect was not accompanied with a reduction in the energetic expenditure during walking in subjects with multiple sclerosis and stroke.
**Level of Evidence:** To be determined.

## Introduction

Loss of neuromuscular control of the ankle joint is a common impairment in neurologic conditions, such as multiple sclerosis [1], stroke [2], and traumatic brain injury [3]. Damage to the motor cortex or corticospinal tract and variability in the area of lesion and the degree of pathology often result in a significant persistent distal weakness. Patients with this pattern often are unable to actively dorsiflex the foot during the swing phase of gait [4]. The deficit of motor control in the ankle joint, typically because of a combination of weakness of the agonist ankle dorsiflexors muscles and spasticity of the antagonist plantarflexor muscles [5], results in slower and abnormal gait and leads to gait compensation strategies consisting of hip hitching, circumduction, and toe catch [6]. Inefficient gait pattern also contributes to slow walking, high energy expenditure, reduced foot clearance, and muscles [7] that may result in a greater chance of stumbling and falling [8].

Loss of neuromuscular control of the ankle joint during the swing phase traditionally is treated by an ankle foot orthosis, but functional electrical stimulation (FES) has been developed as an alternative treatment

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[9]. Previous studies in which authors assessed FES have demonstrated that the common peroneal nerve stimulates the tibialis anterior muscle to produce foot dorsiflexion during the swing phase of the gait cycle and reduces foot drop by facilitating increased voluntary muscle activity, which improves the quality and symmetry of gait [5]. In addition, others studies that investigated the effect of FES have shown improved walking speed and energy in subjects with stroke [10,11] and multiple sclerosis [12,13].

Limited information, however, is available on the effects of this device on reducing falls and on the kinematics changes in lower limbs. No studies have investigated an important kinematic parameter, such as foot clearance (defined as the minimum distance between the foot and the ground during the swing phase of the gait [14]), which has been found to be a common cause of falling in patients with multiple sclerosis and stroke [5,15]. Moreover, to the best of our knowledge, no studies have investigated other parameters, such as energy recovery (defined as the exchange between potential and kinetic energy in the movement of the centre of mass during walking). Energy recovery is associated with changes in gait speed observed with FES treatment [16]. Therefore, the aims of this study were to assess (1) the effectiveness of FES on reducing falls, (2) the effectiveness of FES on improving foot clearance and lower limbs kinematics, and (3) the effectiveness of FES on promoting energy recovery.

## Methods

### *Participants*

A consecutive sample of 24 subjects with upper motor neuron lesions was recruited. The sample was comprised 10 people with stroke and 14 people with multiple sclerosis. The subjects were recruited from the outpatient/inpatient rehabilitation service of the Don Gnocchi Foundation.

Subjects were included in this study if they met the following inclusion criteria: diagnosis of chronic stroke (more than 6 months) or multiple sclerosis with at least 90° of passive dorsiflexion at the ankle and the ability to walk at least 10 meters independently or with a cane, a Mini Mental State Examination [17] score greater than 24, aged between 18 and 80 years, and willingness to participate in the study.

Subjects were excluded if they had a cardiac pacemaker, skin lesion at the site of the stimulation electrodes, Modified Ashworth Scale [18] score of the calf muscles that was more than 4, severe weight-bearing pain, any pre-existing conditions that affected walking function, diagnosis of depression or psychotic disorder, or inability to elicit significant muscular contraction of tibialis anterior at baseline.

The study was conducted in accordance with the Declaration of Helsinki and was approved by the ethics committee of the Don Gnocchi Foundation. Subjects signed an informed consent form before the beginning of the study.

### *Primary Outcomes*

According to the aims of this study, the primary outcome measures were number of falls, foot clearance, and energy recovery factor. The number of falls during the study was monitored prospectively for 8 weeks by the use of a diary. Participants also were interviewed to recall the number of falls in the 2 months before their study participation. The fall was defined as "an episode of unintentionally coming to rest on the ground or lower surface that was not the result of dizziness, fainting, sustaining a violent blow, loss of consciousness or other overwhelming external factors" [19].

Foot clearance, lower limbs kinematics, and energy recovery factor were assessed with the use of instrumented gait analysis on the subsample of 10 people (5 people with stroke and 5 people with multiple sclerosis). Subjects were recorded while walking in the laboratory wearing comfortable shoes at their own comfortable speed without FES at baseline. The test was repeated 4 weeks later in the same condition with and without FES. The SMART motion analysis system (BTS S.p.A., Milan, Italy) and Lamb protocol [20] were used to assess the 3-dimensional kinematics of the subject's lower limbs. Foot clearance, defined as the distance between the foot and the ground at minimum clearance during the swing phase, was measured [8]. To understand the contribution of each joint in determining foot clearance, hip elevation, hip flexion, knee flexion, and ankle dorsiflexion were calculated at the minimum clearance value [21]. Step length and ankle dorsiflexion at initial contact also were recorded.

Energy recovery factor was computed as described by Cavagna et al [16], and it is defined as the percentage of mechanical energy recovered via exchange between kinetic and potential energy in the centre of mass movement.

$$\text{Energy recovery factor} = (W_{ne} - W_{ext})/W_{ne} * 100,$$

where $W_{ne}$ is the maximum work one should do without energy shift, and $W_{ext}$ is the work actually performed. A 100% recovery means a perfect transfer between kinetic and potential energy; healthy subjects have an energy recovery of 65% while walking at 4 km/h [16].

### *Clinical Assessment*

Gait measures were assessed in terms of walking speed by the 10-meter walking test (10-MWT) and walking endurance by the 6-minute walk test (6-MWT).

For the 10-MWT, the subjects were instructed to walk for 10 meters at their comfortable speed with and without FES. Gait speed reflects aspects of walking abilities and commonly is used to measure mobility in people with neurologic dysfunction [22,23]. For 6-MWT, the subjects were instructed to walk at their usual speed for 6 minutes. The distance they covered in 6 minutes was recorded. This is an endurance measure in people with stroke [24] and in people with multiple sclerosis [25]. For 10-MWT and 6-MWT, subjects walked twice with and without FES. For every subject, the trials were conducted in a randomized order with 10 minutes' rest between the 2 tests. Manual Muscle Test [26] was used to assess the ankle dorsiflexors strength, with a score ranging from 0 to 5 where 0 indicates no muscle recruitment and 5 indicates full muscle strength against external resistance.

Fugl-Meyer (lower limbs) [27] was used to assess motor function with a score ranging from 0 to 100, where 100 means best performance, sensory function, balance, joint range of motion, joint pain, and each item is graded on a 3-point ordinal scale (0 = cannot perform; 1 = performs partially; 2 = performs fully) with a maximum score of 100.

Two subscales of the Stroke Impact Scale were used [28]: mobility (best score = 20) and daily living (best score = 45). For each item on this scale, individuals were asked to rate the level of difficulty of the item in the past 2 weeks (1 = could not do it at all, 2 = very difficult, 3 = somewhat difficult, 4 = a little difficult, 5 = not difficult at all).

### *Experimental Procedures*

The study protocol is shown in Figure 1.

*Visit 1: Baseline*

The participants were assessed for the following outcomes: number of falls, instrumented gait analysis, and clinical assessment. Furthermore, subjects received the equipment, the training schedule, and were shown how to use the device. A daily diary was used to record the training time and any adverse events.

*Visit 2: 4 Weeks*

After 4 weeks, subjects returned to the hospital and repeated the instrumented gait analysis and clinical measures.

*Visit 3: 8 Weeks*

Finally, at 8 weeks, subjects brought back their falls diary and repeated all clinical measures.

### *Walking Training Protocol*

Subjects were asked to walk daily using FES daily for a total of 8 weeks. Training time was increased according to the following schedule: the first week, the subjects wore the device for 15 minutes to 1 hour according to individual tolerance, in the second week, for 30 minutes to 4 hours and in the third week, subjects were asked to wear the device for as long as possible. From the third week until the eighth week, participants maintained the training schedule achieved in week 3. The device used in the study was the L300 for Foot Drop FES (Bioness Inc, Valencia, CA), which was cleared by the U.S. Food and Drug Administration. It delivers electrical pulses to the common peroneal nerve throughout the swing phase of gait, leading to ankle dorsiflexion. An expert clinician set the device intensity and pulse frequency to obtain an optimal dorsiflexion response [29].

### *Statistical Analysis*

Results were presented as the mean ± standard deviation for normally distributed variables and median ± interquartile range for non-normally distributed variables. The Wilcoxon signed rank test was used to analyze a statistically significant difference in the number of falls between baseline and 8 weeks. For the foot clearance, lower limbs kinematics and energy recovery factor, the comparisons between performances with FES and without FES were conducted on data from the treated leg. Data were tested for normality and were analyzed with repeated-measures analysis of variance (ANOVA). Statistically significant differences between groups were assessed with the Newman—Keuls post hoc test. The total effect (baseline without FES versus 4 weeks with FES), walking training effect (baseline without FES versus 4 weeks without FES), and 4-week without FES versus 4-week without FES were calculated.

For clinical assessment, nonparametric Friedman ANOVA and Friedman ANOVA post-hoc tests were used. Similar to instrumented gait analysis, we calculated the total effect, walking training effect, and orthotic effect. We used a per-protocol analysis and an intention-to-treat analysis on clinical measures. Because no differences were observed between the per protocol and intention-to-treat analysis, we reported results pertaining to the intention-to-treat analysis. In the case of missing data, a last observation carried forward procedure has been used. The level of statistical significance test was set at $P < .05$.

## Results

Twenty-four subjects were included in the study. At 4 weeks, 2 subjects dropped out, one because of a relapse of multiple sclerosis and one because of knee pain. At 8 weeks, one additional subject dropped out for unknown reasons, leaving a total of 21 people at the end of the study. Patient characteristics are shown in Table 1. A subgroup of 10 people performed

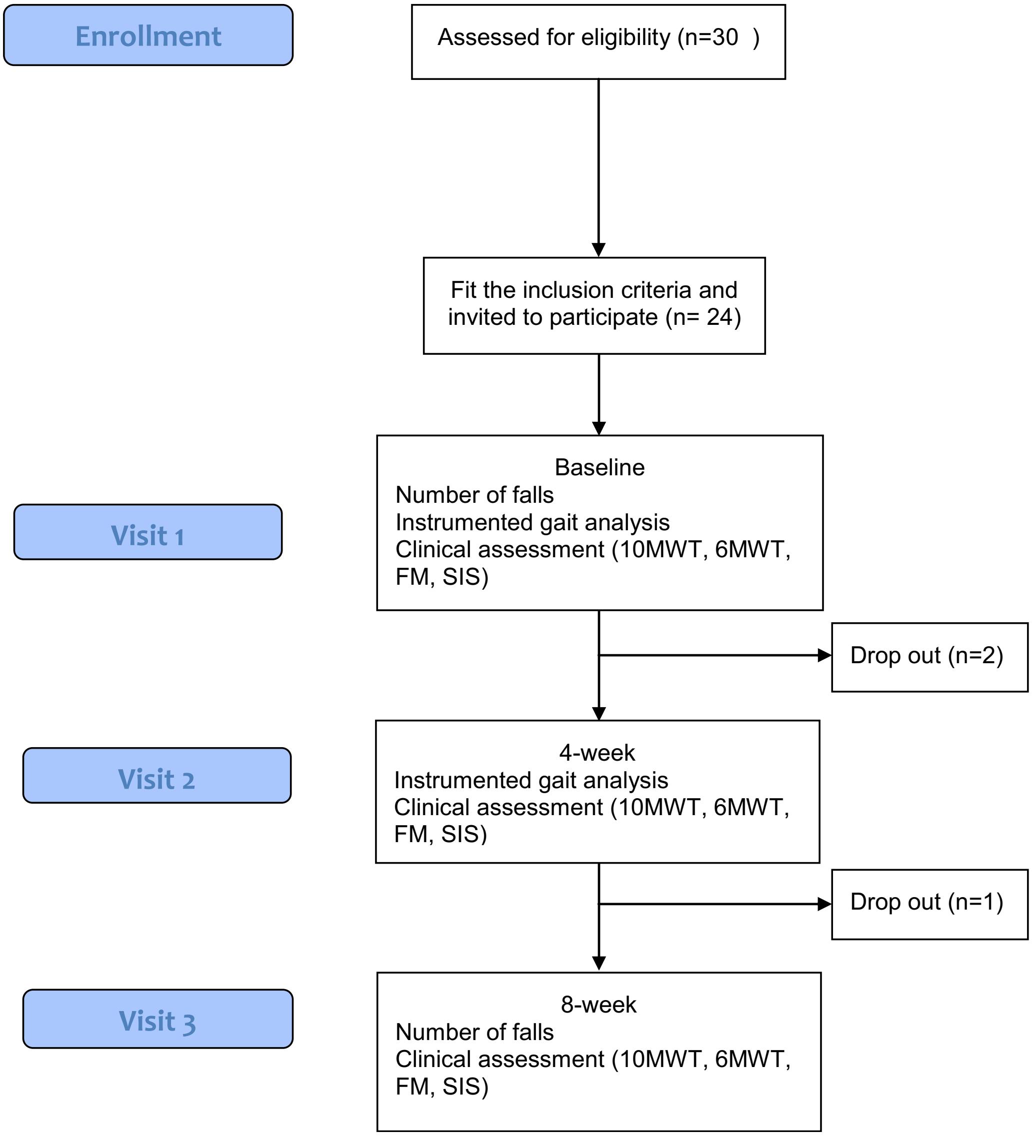


**Figure 1.** CONSORT flow diagram shows 1 the protocol of the study. 10-MWT = 10-meter walking test; 6-MWT = 6-minute walk test; FM = Fugl-Meyer; SIS = Stroke Impact Scale.

instrumented gait analysis, and the characteristics of this subsample are also presented in Table 1.

### *Effectiveness of FES on the Primary Outcomes*

Ten falls were recorded at baseline and 2 falls were recorded after 8 weeks of walking training, showing a statistically significant reduction in the number of falls compared with the baseline, $P = .02$. The number of fallers (at least 1 fall) and frequent fallers (more than 1 fall) are reported in Figure 2.

There was an overall statistically significant improvement in foot clearance between baseline and 4 weeks. Post hoc analysis showed a significant total effect (+5.26 mm, $P = .03$). In contrast, no statistically significant differences were observed for the walking training effect and the orthotic effect. An overall statistically significant change was observed in ankle dorsiflexion at the initial contact ($P = .05$). No changes were observed in ankle dorsiflexion at clearance (Table 2). Finally, no changes were observed in the energy recovery factor between baseline and the 4-week assessment (Table 2).

### *Effectiveness of FES on Clinical Assessment*

There was a significant overall effect of FES on 10-MWT ($P < .001$, Figure 3). Post hoc comparisons showed differences in the total effect between baseline (without FES) and the 4-week assessment (with FES) and between baseline and the 8-week assessment (with FES). Subjects completed the test 2.63 seconds (4 weeks) and 2.64 seconds (8 weeks) faster than at baseline, corresponding to a change in gait velocity from 0.64 m/s (baseline) to 0.87 m/s (4 weeks) and 0.88 m/s (8 weeks), respectively. Post hoc comparisons also showed a walking training effect between baseline

**Table 1**
Demographic and clinical features of the total sample and subsample

| | People With Multiple Sclerosis | People With Stroke | Total Sample | Subsample |
|---|---|---|---|---|
| Number of subjects | 14 | 10 | 24 | 10 |
| Female n (%) | 7 (50) | 2 (20) | 9 (38) | 3 (30) |
| Age, y | 50.93 (8.72) | 55.38 (14.55) | 52.55 (11.07) | 58.87 (14.01) |
| Time since onset, y | 17.51 (9.41) | 3.09 (2.86) | 11.33 (10.27) | 12.83 (12.60) |
| Affected side (right), n (%) | 12 (86) | 6 (60) | 18 (75) | 7 (70) |
| Assistive device, n (%) | 6 (43) | 9 (90) | 15 (63) | 5 (50) |

Mean (standard deviation) or number (%) are reported.

(without FES) and the 8-week assessment (without FES) and an orthotic effect when subjects walked with and without the FES at baseline $-1.05 \pm 4.02$ seconds ($P >$ .05), 4 weeks $0.99 \pm 2.76$ seconds ($P <$ .05), and 8 weeks $0.88 \pm 4.74$ seconds ($P <$ .05).

There was a significant overall effect of FES on 6-MWT ($P <$ .001, Figure 3). Post hoc comparisons showed differences in the total effect between baseline and the 4-week assessment and between baseline and the 8-week assessment where subjects walked 37 meters (4 weeks) and 38 meters (8 weeks) more than at baseline. Post hoc analysis also showed a walking training effect between baseline and 8-week assessment. At 8 weeks, subjects walked 19 meters more than at baseline and the orthotic effect when subjects walked with and without the FES at baseline was $16 \pm 16$ m ($P >$ .05) at 4 weeks $-23 \pm 24$ meters ($P <$ .05) and 8 weeks $-22 \pm 31$ meters ($P >$ .05). Finally, medians and interquartile ranges of the Manual Muscle Test, Fugl-Meyer, and Stroke Impact Scale at baseline, at 4 weeks, and at 8 weeks are reported in Table 3, showing a statistically significant improvement between assessments.

Means and standard deviations of the kinematic parameters were reported in Supplementary Table 1. Hip and knee motion at clearance, step length, gait speed, and cadence did not show changes between baseline and 4 weeks with and without FES. A total effect (between baseline without FES and 4 weeks with FES) was found in step width ($P =$ .03).

## Discussion

The results of this study demonstrate that in group of patients with multiple sclerosis and stroke, a walking training protocol with FES for 8 weeks benefited individuals with neurologic disorders who had unstable

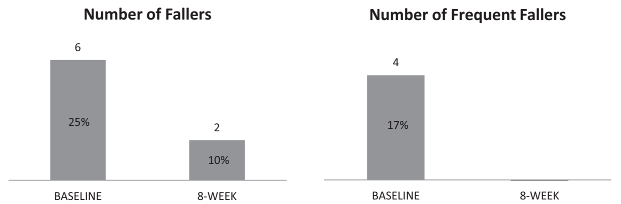


**Figure 2.** Histograms showing number of fallers and frequent fallers at baseline and 8 weeks.

ankle joints, thereby reducing the number of falls and improving walking kinematic parameters without any improvement in energy recovery.

The first result of this study is that the use of FES reduced the number of falls even if subjects were asked to walk for longer than before and to increase their daily activities. This issue is an important one in these 2 pathologies, which show high prevalence of falls leading to fractures and diminished quality of life [30,31]. To understand whether this reduction in number of falls was related to changes in the gait pattern, we examined the effects of FES on foot clearance and in lower limbs kinetic variables [32,33]. We found an improvement in clearance after 4 weeks of training, providing evidence to support the link between foot clearance and trips and slips due to lack of control of the ankle muscles [34] leading to an abnormal position of the foot and its premature contact with the ground [35].

The second result of this study is that the improvement in foot clearance was attributable to increased ankle dorsiflexion with a small contribution at knee and hip level. This finding suggests that the FES had a specific effect at the ankle and that the increase of clearance was not due to compensatory movements at proximal joints. Increased dorsiflexion also was evident at initial contact, improving the ability to place the foot in the right position with respect to the ground avoiding premature forefoot contact and promoting foot evertion during mid swing. Our results are in agreement with the study of Van der Linden et al [12], in which subjects gained 2.6° at the ankle joint during gait with FES, and with the study of Yao et al [36], in which dorsiflexion increased in stroke patients on average from 1.3° to 11.6° during initial contact as well as from 11.3° to 17.0° during mid swing.

The third result is that the use of FES did not improve energy recovery, resulting in a less-efficient exchange between kinetic and potential energy. This finding could be partially attributable to the small differences in energy recovery between our sample and healthy subjects walking slowly [37], suggesting that the basic energy recovery mechanism already was exploited partially. It is also possible that even with FES, subjects did not properly place the foot in the right position to use the heel as a pivot at foot strike, conserving the momentum generated at push-off to propel the center of mass forward and up favoring the

**Table 2**
Instrumented gait analysis: foot clearance, lower limbs kinematic, and energy recovery factor

| | Baseline Without FES | 4-Week Without FES | 4-Week With FES | Overall *P* Value | Post-Hoc Total Effect (Baseline Without FES vs 4-Week With FES) |
|---|---|---|---|---|---|
| Clearance, mm | 17.06 (6.93) | 19.97 (8.34) | 22.06 (8.91) | .04 | 5.26 (7.16) *P* = .03 |
| Ankle dorsiflexion at the initial contact, °* | −42.08 (8.53) | −43.78 (9.61) | −37.89 (6.82) | .05 | 5.08 (7.18) *P* = .08 |
| Ankle dorsiflexion at clearance, °* | −39.76 (8.02) | −41.83 (10.11) | −35.97 (8.08) | .08 | 3.79 (7.79) *P* = .14 |
| Energy recovery factor, % | 43 (1) | 43 (2) | 45 (1) | .53 | −2 |

Means (standard deviations) are reported.
Overall *P* value: analysis of variance *P* values across means.
* Greater values indicate increase of ankle dorsiflexion.

exchange between kinetic and potential energy at heel strike [38]. In addition, it has been suggested that FES of the dorsiflexors alone does not address other critical gait deficits, such as reduced push-off forces and ankle plantar flexor moment during terminal stance. Recent work has shown that delivering FES to ankle dorsi and plantarflexors increases the production of external mechanical energy improving energy recovery of stroke patients [39]. Finally, reduction in falls and improvement in ankle dorsiflexion were associated with changes in endurance and gait speed, reduction of impairments and increased independence in activity of daily living.

Previous studies reported improvements in walking endurance for periods ranging from 6 to 30 weeks [8]. Our data suggest that a period of 8 weeks is optimal to achieve a clinically meaningful effect on walking endurance. After the training, subjects walked almost 40 meters farther than at baseline on 6-MWT. According to Baert et al [40], an improvement greater than 21.6 m can be considered clinically relevant for people with multiple sclerosis. Improvement in walking endurance also was

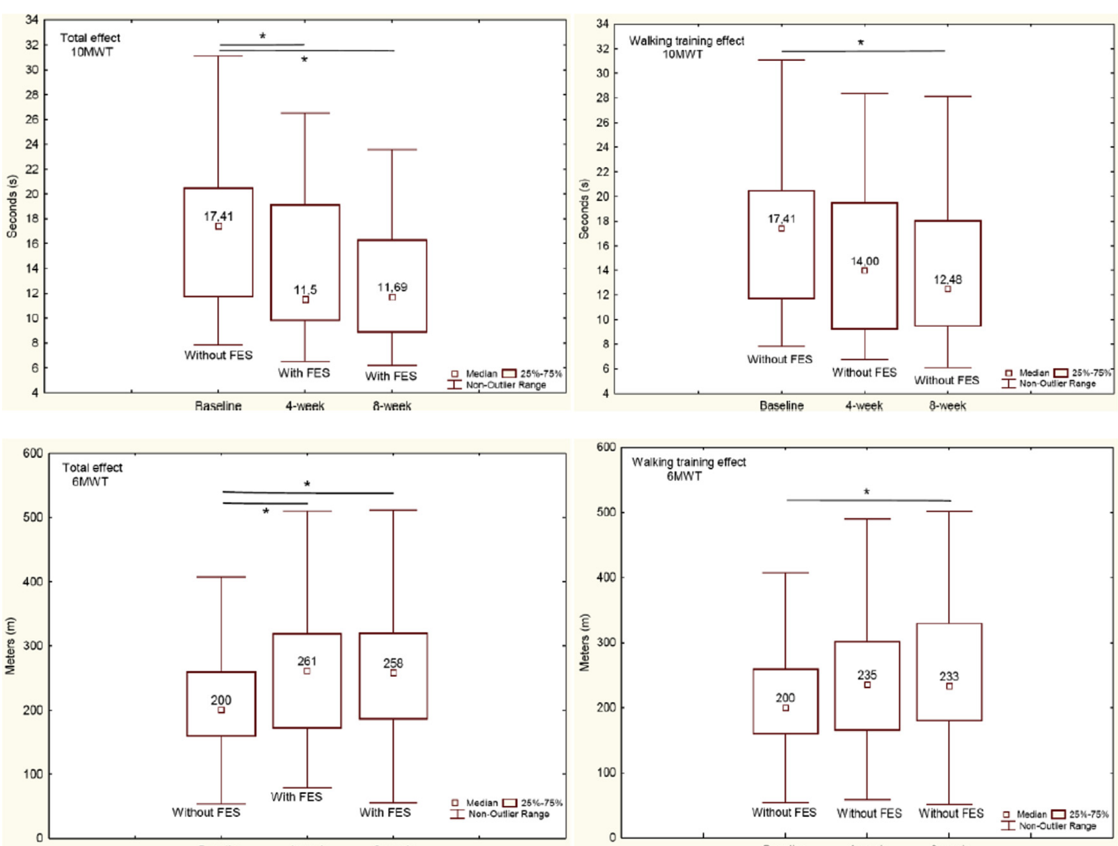


**Figure 3.** Total effect and walking training effect of 10MWT and 6MWT at baseline, 4-week, 8-week. 10MWT = 10-meter walking test; 6MWT = 6-minute walking test; With FES = functional electrical stimulation device switched on; Without FES = functional electrical stimulation device switched off; 4-week = assessment after 4 weeks; 8-week = assessment after 8 weeks.

Table 3
Medians and IQR of clinical outcomes at baseline, at 4 weeks, and at 8 weeks

| | Baseline Median (IRQ) | 4-Week Median (IRQ) | 8-Week Median (IRQ) | Overall *P* Value |
|---|---|---|---|---|
| MMT | 2 (2) | 2 (2) | 2 (1) | .02 |
| FM | 74.00 (17.25) | 81.00 (18.75) | 82.50 (15.50) | <.001 |
| SIS Mob | 35.00 (11.50) | 36.00 (6.50) | 37.00 (6.25) | <.001 |
| SIS Adl | 13.05 (6.25) | 15.00 (5.00) | 16.00 (6.00) | <.001 |

IQR = interquartile range; MMT = Manual Muscle Test; FM = Fugl-Meyer; SIS Mob = Stroke Impact Scale Mobility; SIS Adl = Stroke Impact Scale Activity Daily Living.

Overall *P* value: Friedman analysis of variance's *P* values across medians.

accompanied by greater walking speed at 10-MWT than the baseline. These improvements can be considered clinically relevant since people with stroke crossed the cut-off score (0.66 m/s) discriminating noncommunity walkers from community walkers [41], whereas people with multiple sclerosis did not reach the threshold (>1.04 m/s) to pass from unlimited household walker to most-limited community walker [42]. After training, subjects improved walking endurance even without the device. These results are consistent with the findings reported by Kottnik et al [8] and Robbins et al [43], suggesting the walking protocol increased subjects' resources independently from the use of the device. Interestingly, we did not observe statistically significant changes when comparing subjects' performance with and without FES at baseline (orthotic effect). On the other hand, significant improvements were observed at 4 and 8 weeks. This suggests that a treatment protocol should always be performed before the prescription of the device.

After training motor impairments decreased, the muscle strength of the tibialis anterior was increased, as revealed by the Manual Muscle Test, and ankle attitude and movements of the lower limbs improved, as suggested by changes in the Fugl-Meyer scale. These results are consistent with the findings reported in a review by Glinsky et al [44], indicating that electrical stimulation can be effective for increasing voluntary muscle strength in people with stroke. These results were accompanied by a small but a statistically significant increase in independence in activity of daily living as revealed by improvement in mobility (eg, walking outside, walking faster and going up the stairs) and activity of daily living (eg, doing light housekeeping and going shopping), corroborating the results observed by Kluding at al [4] within a group of stroke patients treated with FES.

There are several limitations to this study that need to be addressed.

First, the study sample is small and without a control group. Studies on a larger sample with an instrumented and clinical assessment are warranted to apply these results to a larger population. Second, an instrumented assessment should be added at 8 weeks to understand whether the same results were maintained during the entire protocol. Third, a longer follow-up period could be useful to evaluate long-lasting effects of FES and adherence.

## Conclusions

The use of FES had an impact on gait, reducing the number of falls and improving walking. A specific effect at the ankle joint was observed, increasing foot clearance during the swing phase of gait. This effect was not accompanied by a reduction in the energetic expenditure during walking in subjects with multiple sclerosis and stroke.

## Supplementary Data

Supplementary data associated with this article canbe found in the online version at http://dx.doi.org/10.1016/j.pmrj.2016.10.019.

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## Disclosure

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**Supplementary Table 1**
Kinematic analysis of hip, knee motion, step width, step length, gait speed, and cadence

| | Baseline Without FES | 4-Week Without FES | 4-Week With FES | Overall *P* Value | Total Effect (Baseline Without FES vs 4-week With FES) |
|---|---|---|---|---|---|
| Knee flexion at clearance, ° | 23.07 (9.12) | 26.41 (10.60) | 25.45 (11.33) | .23 | 2.37 (6.35) |
| Hip flexion at clearance, ° | 24.24 (5.17) | 26.14 (9.52) | 25.05 (10.31) | .57 | 1.97 (5.80) |
| Hip elevation at clearance, ° | −4.97 (3.82) | −5.30 (3.95) | −4.46 (3.41) | .51 | 0.51 (2.75) |
| Step width, mm | 196.79 (24.72) | 171.70 (30.10) | 182.75 (41.85) | .03 | 25.09 (22.59) $P = .03$ |
| Step length, % body height | 54.58 (6.90) | 52.91 (6.73) | 52.22 (6.49) | .07 | 1.66 (2.34) |
| Gait speed, % body height/s | 27.27 (8.23) | 31.26 (13.65) | 29.49 (14.21) | .44 | 3.84 (11.55) |
| Cadence, steps/min | 35.47 (6.25) | 38.13 (9.44) | 36.91 (9.69) | .38 | 2.65 (7.31) |

FES = functional electrical stimulation.
Means (standard deviations) are reported.
Overall *P* value: analysis of variance's *P* values across medians.